PATENT
Docket No. ARC2865N1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	LAM et al.	)	Group Art Unit: Unknown
Serial No.:	Unassigned (Parent: 09/253,317)	)	Examiner: Unknown
Filed:	Herewith (Parent: February 19, 1999)	)	

For: METHODS AND DEVICES FOR PROVIDING PROLONGED DRUG THERAPY

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
ATTN: Box Patent Application
Washington D.C. 20231

Sir:

Prior to taking up the above-identified patent application for examination, please amend the specification as follows:

In the Specification

Please delete paragraph **[0001]** and insert therefore new paragraph **[0001]** as follows:

[0001] This application is a continuation of U.S. Application No. 09/253,317, filed February 19, 1999, which is a continuation-in-part of U.S. Application No. 09/070,666, filed April 30, 1998, which is a continuation of U.S. Application No. 08/910,593, filed July 31, 1997, which claims the benefit of U.S. Provisional Application Nos. 60/030,514 and 60/044,121, filed November 12, 1996 and April 22, 1997, respectively.

In the Claims

Please cancel claims 1 and 3-47.

Please add the new claims 48-58:

48. A method for lessening the incidence of tolerance to methylphenidate administered to an Attention-Deficit Disorder patient who develops tolerance to methylphenidate, wherein the method comprises administering orally to the patient a dosage form tablet that delivers 100 ng to 500 mg of methylphenidate in a sustained and increasing dose over 16 hours to produce the intended effect.

49. A method for lessening the incidence of tolerance in a patient having Attention-Deficit Disorder, wherein the method comprises administering a pharmaceutically acceptable composition comprising 100 ng to 500 mg of methylphenidate and a pharmaceutically acceptable carrier, that is administered in a sustained and increasing dose for lessening the incidence of tolerance in the patient.

50. A method for treating Attention-Deficit Disorder in a patient, wherein the method comprises administering a pharmaceutically acceptable composition comprising 100 ng to 500 mg of a member selected from the group consisting of amphetamine, dextroamphetamine, methamphetamine, phenylisopropylamine, and pemoline, and a pharmaceutically acceptable carrier, in a sustained and increasing dose for treating Attention-Deficit Disorder in the patient.

51. A method for maintaining the therapeutic effect of methylphenidate in an Attention-Deficit Disorder patient who acquires tolerance to methylphenidate, wherein the method comprises administering orally to the patient a dosage form tablet comprising 100 ng to 500 mg of methylphenidate that delivers the methylphenidate in a controlled and increasing dose over 16 hours to maintain the therapeutic effect in the patient.

52. A method for compensating for a decrease in the therapeutic effect to methylphenidate in an Attention-Deficit Disorder patient, wherein the method comprises administering a dosage form tablet comprising 100 ng to 500 mg of methylphenidate to the patient that administers the methylphenidate in a continually-ascending rate over 16 hours to compensate for the decrease in the therapeutic effect.

53. A method for treating Attention-Deficit Disorder in a human, wherein the method comprises administering orally to a human having Attention-Deficit Disorder a dosage form that administers a sustained and continuously ascending dose of 100 ng to 500 mg.

54. A method of treating Attention-Deficit Disorder in a human wherein the method comprises administering orally to a human having Attention-Deficit Disorder a dosage form that administers a sustained and continuously ascending dose of 5 mg to 75 mg over 12 hours of a drug selected from the group consisting of methylphenidate and its pharmaceutically acceptable salts for treating Attention-Deficit Disorder in the human.

55. A method of treating Attention-Deficit Disorder in a human, wherein the method comprises administering orally to a human having Attention-Deficit Disorder a dosage form that administers a sustained and continuously ascending dose of 100 ng to 500 mg over 16 hours of a drug selected from the group consisting of amphetamine, dextroamphetamine, methamphetamine, threomethylphenidate, phenylisopropylamine, and pemoline for treating Attention-Deficit Disorders in the human.

56. A method for the management of Attention-Deficit Disorder and Attention-Deficit Hyperactivity disorder in a patient, wherein the method comprises administering orally to the patient a dosage form comprising 100 ng to 500 mg of methylphenidate that is administered in a sustained and continuously ascending dose throughout a school day for the management of Attention-Deficit Disorder and Attention Deficit Hyperactivity Disorder in the patient.

57. A dosage form tablet for treating Attention-Deficit Disorder comprising 100 ng to 500 mg of methylphenidate in admixture with a pharmaceutically acceptable carrier that release the methylphenidate in a sustained and increasing dose for treating Attention-deficit Disorder.

58. A dosage form tablet for treating Attention-Deficit Hyperactivity Disorder, comprising 100 ng to 500 mg of a member selected from the group consisting of methylphenidate and its pharmaceutically acceptable salts mixed with a pharmaceutically acceptable carrier that is delivered in a controlled and increasing dose for treating Attention-Deficit Hyperactivity Disorder.

REMARKS

The specification has been amended, i.e., paragraph **[0001]**, to claim priority to parent application, U.S. Application No. 09/253,317.

Claims 1 and 3-47 have been canceled and claims 48-58 have been added. Upon entry of the Preliminary Amendment, claims 2 and 48-58 should be pending in the above-identified patent application.

Applicants bring to the Examiner's attention withdrawn U.S. Patent No. 6,034,101 (courtesy copy enclosed herewith). The claims previously allowed in U.S. Patent No. 6,034,101 (claims 1-11), are the claims now presented by preliminary amendment. This application claims priority to this withdrawn patent, i.e., U.S. Application No. 08/910,593, filed July 31, 1997.

No new matter has been added by these amendments.

The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if there are any questions regarding the above new claims or if prosecution of this application may be assisted thereby.

Respectfully submitted,
LAM et al.,
By his Representatives,
ALZA Corporation
1900 Charleston Road
Mountain View, CA 94043
(650) 564-5000

08 MARCH 2001
Date

By: Paul B. Simboli
Paul B. Simboli
Reg. No. 38,616
Attorney for Applicants
Direct Dial: (650) 564-7840

PBS/KMG

METHODS AND DEVICES FOR PROVIDING PROLONGED DRUG THERAPY

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. Application No. 09/253,317 filed February 19, 1999, which

[0001] This application is a continuation-in-part of U.S. Application No. 09/070,666, filed April 30, 1998, which is a continuation of U.S. Application No. 08/910,593, filed July 31, 1997, which claims the benefit of U.S. Provisional Application Nos. 60/030,514 and 60/044,121, filed November 12, 1996 and April 22, 1997, respectively.

[0002] This application is also a continuation-in-part of U.S. Application No. 08/967,606, filed November 10, 1997, which claims the benefit of U.S. Provisional Application No. 60/031,741, filed November 25, 1996.

[0003] This application is also a continuation-in-part of U.S. Application No. 08/937,336, filed August 19, 1997.

BACKGROUND OF THE INVENTION

Field of the Invention

[0004] This invention pertains to methods and devices for maintaining a desired therapeutic drug effect over a prolonged therapy period. In particular, the invention is directed to methods and devices that provide drug release within the gastrointestinal tract at an ascending release rate over an extended time period. In this manner, drug is released at an ascending rate during a portion of the drug administration period sufficient to maintain a desired therapeutic drug effect throughout a prolonged therapy period.

[0005] Description of the Related Art Including Information Disclosed Under 37 CFR 1.97 and 1.98

[0006] To produce its pharmacological effects, a drug must be made available in appropriate concentrations at its site of action within the body. This availability is affected by numerous factors including the quantity of the drug administered, the extent and rate of its absorption from its administration site, its distribution, binding or localization within tissues, its biotransformation